APR 15 2005

K042927

October 21, 2004

510(k) SUMMARY

CONTACT:

Douglas L. Harris
Greiner Vacuette North America, Inc.
P.O Box 1026
Monroe, NC 28111

NAME OF DEVICE:

Trade Name:	Vacuette® EDTA K3 Tubes
Common Names/Descriptions:	Evacuated Blood Collection System
Classification Name:	Tubes, Vials, Systems, Serum Separators, Blood Collection

PREDICATE DEVICE: Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube (K972075) and Glass K_3 EDTA Tube (pre-amendment)

DEVICE DESCRIPTION:

INTENDED USE: VACUETTE® Tubes, Holders and Needles are used together as a system for the collection of venous blood. VACUETTE® tubes are used to collect, transport and process blood for testing serum, plasma or whole blood in the clinical laboratory. VACUETTE® EDTA K3 Tubes are used for testing whole blood in molecular diagnostics.

SUBSTANTIAL EQUIVALENCE:

The VACUETTE® EDTA K3 Tube and the Becton Dickinson Vacutainer® Brand PPT™ Plasma Preparation Tube and Glass K_3 EDTA Tube are substantially equivalent in intended use, design and composition.

Studies were conducted to demonstrate substantial equivalence of the Greiner VACUETTE® EDTA K3 Tube to the Becton Dickinson (BD) Vacutainer® Brand PPT™ Plasma Preparation Tube and Glass K_3 EDTA Tube when samples from these tubes are used in molecular diagnostic (nucleic acid PCR) assays.

The conclusion from the studies were that the HIV-1 and HCV PCR results from the apparently healthy blood donors' and patients' samples collected in the Greiner and BD tubes were substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 15 2005

Greiner Bio-One North America, Inc.
c/o Sienna Partners, L.L.C.
Judi Smith
Principal
P.O. Box 103
Baldwin, MD 21013

Re: k042927
Trade/Device Name: Greiner VACUETTE® EDTA K3 Evacuated Blood Collection Tubes
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: Class II
Product Code: JKA
Dated: March 1, 2005
Received: March 3, 2005

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K042927

Device Name: Greiner **VACUETTE**® EDTA K3 Evacuated Blood Collection Tubes

Indications For Use:

VACUETTE® Tubes, Holders and Needles are used together as a system for the collection of venous blood. VACUETTE® EDTA K3 Tubes are used for testing plasma in molecular diagnostics. The performance characteristics of this device have not been established for molecular diagnostic assays in general. Users must validate use of product for their specific molecular diagnostic assay.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

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